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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/527,785	03/17/2000	Oleg N. Suslov	4350.001200	3947

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EXAMINER	
HAYES, ROBERT CLINTON	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 02/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/527,785	SUSLOV ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *56-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *56-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 56-58 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/17/03 has been entered.

2. Newly submitted claim 56-58 (in part) are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

It is noted that Applicants elected without traverse the invention of Group IIv (glioma cDNA libraries) in Paper No.18. In contrast, the nonelected neural stem cell cDNA libraries were Group IIii, the nonelected neuronal progenitor cell cDNA libraries were Group IIiii, and the nonelected glial progenitor cell cDNA libraries were Group IIiv.

Moreover, it is noted that the Examiner had allowed this new election after Applicants' amendment of the claims to previously overcome the rejection under 102(a) of claims 2-5 & 12-21 as being anticipated by Cytotherapeutics, Inc (WO 99/11758; Suppl. IDS Ref # B1) from Paper No: 14 (mailed 6/17/03), as it related to cDNA libraries from neurospheres (i.e., containing the neural stem cells and progenitor cells of Groups IIii-iv).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 56-58 (in part, as it relates to stem and progenitor cells) are

withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

This application contains claims 56-59 (in part, as it relates to stem and progenitor cells) drawn to an invention nonelected with traverse in Paper No. 18. A complete reply to the final rejection from Paper No: 19 (mailed 7/16/03) must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Applicants' arguments filed 12/17/03 have been fully considered but they are not deemed to be persuasive.

5. Claims 56-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No proper antecedent basis nor conception in context with that described within the instant specification at the time of filing this application exists for the recitation of "a cDNA library produced from a glioma tumor stem or progenitor cell". For example, the description on pages 46 & 47 specifically distinguishes "primary gliomas" from "normal human brain stem and

progenitor cells", and distinguishes "[s]tem and tumor cells". In other words, neural stem cells are neural stem cells. Neuronal progenitor cells are neuronal progenitor cells. Glial progenitor cells are glial progenitor cells. And importantly, glioma tumor cells are glioma tumor cells. Thus, no glioma tumor stem or progenitor cells exist in the art, nor are such reasonably contemplated within the specification; thereby, constituting new matter.

Likewise, in contrast to Applicants' assertions on page 4 of the response, no proper basis exists for using the gene transcripts listed in Table 3 on page 43 of the specification for providing proper basis for the limitations of "markers of neuronal lineage" or "markers for glial lineage" recited in new claims 56-58. In contrast, Table 3 lists gene transcripts from "neurosphere" "clones", which alternatively contain neural stem cells, neuronal progenitor cells and glial progenitor cells; and not glioma tumor cells. Thus, mixing and matching different and unique characteristics for gene expression patterns observed in neural stem and neural progenitor cells, and not glioma tumor cells, is improper. In other words, "individual profiles of gene expression [that are putatively] *similar* to those of normal human brain stem and progenitor cells [emphasis added]" is not equivalent in scope nor conception to what gene transcripts are expressed in glioma tumor cells, which appears to include "β-III tubulin" and "GFAP" expression, as disclosed on page 47 of the specification; thereby, also constituting new matter for both the generic expression now claimed (i.e., "markers of neuronal lineage" or "markers for glial lineage") and for the specific markers, "neuron-specific enolase, neurofilament M, tenasin, MAP2" and "nestin".

6. Claims 56-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Danik et al (1991), for the reasons made of record in Paper No: 19 (mailed 7/16/03), and as follows.

Applicants argue on pages 3-6 of the response that the claims now recite "a cDNA library produced from a glioma tumor stem or progenitor cell", and that Danik et al. do not teach such. However, in contrast to Applicants' assertions, the elected invention without traverse was cDNA libraries from a glioma tumor cell. Thus, the instant rejection is maintained for the reasons made of record, because glioma tumor cells are glioma tumor cells, just like that taught by Danik et al., and because no glioma tumor stem or progenitor cells exist in the art, as claimed. *In arguendo,* as previously made of record, the gene transcripts expressed by glioma tumor cells is an inherent property of glioma tumor cells, which inherently includes "encoding at least one marker of neuronal lineage and at least one marker of glial lineage" (such as any housekeeping gene transcript, actin, etc., etc.) as required for every cell's survival (i.e., including glioma tumor cells); absent evidence to the contrary, which Applicants have failed to provide.

In addition, as previously made of record, the cDNA libraries from Danik's glioma tumor cell clones inherently express the same gene transcripts as any "plurality of cells" from the "progeny of a single glioma tumor... cell", because it is well known in the art that glioma tumorigenesis is the result of a single cell being transformed into uncontrolled growth into a "plurality of cells"; thereby, further reasonably meeting the product-by-process claim limitation of "isolated from a microclone comprised of a plurality of cells, each cell of which is the progeny

of a single glioma tumor... cell". Thus, Applicants' arguments are not on point, and therefore, moot.

In summary, Danik et al. teach a cDNA library from a human glioma (pg. 8578, 1st col.), which is a collection of expressed gene transcripts from a plurality of cells that are the progeny of a single glioma tumor cell, by definition, and as claimed.

The issue then becomes that if the product in a product-by-process claim (i.e., a cDNA library produced by a microclone comprised of a plurality of cells) is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. *In re Thorpe.*, 227 USPQ 964, 966 (Fed. Cir. 1985): *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983). In addition, it has been established by the courts that a product (i.e., the cDNA library) inherently possesses characteristics of that product (i.e., the gene transcripts/markers expressed), and that:

"the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Accordingly, since the issue in the present appeal is whether the prior art factor is identified or patently indistinct from that of the material on appeal, appellants have the burden of showing that inherency is not involved". *Ex parte Gray,* 10 USPQ 2d 1922 (1989); *In re Best,* 195 USPQ 430 (CCPA 1976).

Lastly, it is noted that the courts have held that when the prior art product reasonably appears to be the same as that claimed, but differs by process in which it is produced, a rejection of this nature is eminently fair and the burden is upon the appellants to prove, by comparative evidence, a patentable difference (*In re Brown*, 173 USPQ 685 (1972)).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (571) 272-0887. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

RCH

Robert C. Hayes, Ph.D.
February 25, 2004
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